DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 17, 2015

Belimed Sauter AG
Michael Hari
Head of Medical Engineering
Zelgstrasse 8
CH8583 Sulgen, Switzerland

Re: K141879
Trade/Device Name: Belimed Steam Sterilizer MST-H
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: May 18, 2015
Received: May 20, 2015

Dear Mr. Hari,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number:
K141879

Device Name:
Belimed Steam Sterilizer MST-H

Indications for Use

The Belimed Steam Sterilizers MST-H, models 9-6-12, 9-6-15, and 9-6-18 are designed for sterilization of non-porous and porous heat and moisture-stable materials used in healthcare facilities.
The Belimed Steam Sterilizers MST-H, models 9-6-12, 9-6-15, and 9-6-18 are available in a single door (HS1) or double door (HS2) version.

Type of Use (Select one or both, as applicable)
☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

The Belimed Steam Sterilizer MST-H is offered with the following factory-programmed predefined sterilization cycles:

Cycle	Pre-treatment	Sterilizing temperature	Sterilizing Time 1)	Drying time 2)	Recommended load 3)
PreVac 270 4S/30D	5 pulses	270 °F	4 min	30 min	Double wrapped instrument trays, max. weight of 25 lbs per tray, Fabric packs
PreVac 270 4S/5D	5 pulses	270 °F	4 min	5 min	Fabric packs 4)
PreVac 275 3S/30D	5 pulses	275 °F	3 min	30 min	Double wrapped instrument trays, max. weight of 25 lbs per tray, Fabric packs
Bowie-Dick Test	5 pulses	273 °F	3.5 min	1 min	One Bowie-Dick-Test-Pack
Gravity 270 15S/30D	Purge	270 °F	15 min	30 min	Double wrapped instrument trays, with non-porous instruments, max. weight of 25 lbs per tray
Liquid 250 45S	Purge	250 °F	45 min	0 min	Liquids, up to 1000 ml in vented or open containers 5)
Air leak Test	Vacuum: 65mbar Test time: 15 min	-	-	-	Empty chamber
Warm up & Air Leak Test	Vacuum: 65mbar Test time: 15 min	270 °F	3 min	3 min	Empty chamber
Warm up	2 pulses	270°F	3 min	3 min	Empty chamber

Table 1: Factory programmed Sterilization cycles

Notes for Table 1:
1. Only factory set sterilizing time should be utilized with medical devices intended for patient contact.
2. Factory set drying time. These are the minimum validated drying times, which may be extended depending on load conditions and wraps.
3. Recommended load: Refer to table 2 and 3. The load configurations listed in table 2 and 3 are those used during performance testing of the sterilizer models.
4. Fabric load should be preconditioned between 68°F and 75°F and at a relative humidity of at least 35% to 60% for at least 2 hours.
5. Liquid cycle is not intended to sterilize liquids that are used for direct patient contact.

The following tables show the recommended loads for the Belimed Steam Sterilizer MST-H:

Model	Instrument trays, max. 25 lbs each	Fabric Packs, max. 3.3 lbs each
9-6-12	16	32
9-6-15	20	40
9-6-18	24	48

Table 2: Recommended loads for non-porous and porous load cycles

Model	Volume of liquid in one container	Number of containers
9-6-12	1000 ml	168
9-6-15	1000 ml	210
9-6-18	1000 ml	252

Table 3: Recommended loads for liquid cycle 250 °F

The Belimed Steam Sterilizer MST-H is offered in the following models:

Model	Configuration	Net loading capacity (L)	Chamber size (H x W x D) (mm)	Overall Dimensions (H x W x D) (mm)
9-6-12 HS1	1 door	691	1080 x 660 x 1398	1970 x 1700 x 1714
9-6-12 HS2	2 doors	691	1080 x 660 x 1398	1970 x 1700 x 1714
9-6-15 HS1	1 door	864	1080 x 660 x 1706	1970 x 1700 x 2022
9-6-15 HS2	2 doors	864	1080 x 660 x 1706	1970 x 1700 x 2022
9-6-18 HS1	1 door	977	1080 x 660 x 2014	1970 x 1700 x 2330
9-6-18 HS2	2 doors	977	1080 x 660 x 2014	1970 x 1700 x 2330

Table 4: Models and dimensions

510(k) Summary

Date:	June 10, 2015
Submitter's Name / Address:	Belimed Sauter AG Zelgstrasse 8 CH- 8583 Sulgen / Switzerland
Contact Person:	Michael Hari Email: michael.hari@belimed.ch Phone: +41 71 644 86 37 Fax: +41 71 644 85 11
Trade Name:	Belimed Steam Sterilizer MST-H
Models:	9-6-12, 9-6-15 and 9-6-18
Classification:	Steam Sterilizer – Class II, as listed per 21 CFR 880.6880 Product Code: FLE
Predicate Device:	Belimed Steam Sterilizer TOP 5000 Series 9-18 (K021223)

INTENDED USE:

The Belimed Steam Sterilizers MST-H, models 9-6-12, 9-6-15, and 9-6-18 are designed for sterilization of non-porous and porous heat and moisture-stable materials used in healthcare facilities.

DESCRIPTION OF DEVICE:

The Belimed Steam Sterilizers MST-H, models 9-6-12, 9-6-15, and 9-6-18 are available in a single door (HS1) or double door (HS2) version.

The sterilizers are equipped with Pre-vacuum, Gravity, Liquid, Air Leak Test and Bowie-Dick Test cycles.

The Belimed Steam Sterilizer MST-H is offered with the following factory-programmed predefined sterilization cycles:

Cycle	Pre-treatment	Sterilizing temperature	Sterilizing Time 1)	Drying time 2)	Recommended load 3)
PreVac 270 4S/30D	5 pulses	270 °F	4 min	30 min	Double wrapped instrument trays, max. weight of 25 lbs per tray, Fabric packs
PreVac 270 4S/5D	5 pulses	270 °F	4 min	5 min	Fabric packs 4)
PreVac 275 3S/30D	5 pulses	275 °F	3 min	30 min	Double wrapped instrument trays, max. weight of 25 lbs per tray, Fabric packs
Bowie-Dick Test	5 pulses	273 °F	3.5 min	1 min	One Bowie-Dick-Test-Pack
Gravity 270 15S/30D	Purge	270 °F	15 min	30 min	Double wrapped instrument trays, with non-porous instruments, max. weight of 25 lbs per tray
Liquid 250 45S	Purge	250 °F	45 min	0 min	Liquids, up to 1000 ml in vented or open containers 5)
Air leak Test	Vacuum: 65mbar Test time: 15 min	-	-	-	Empty chamber
Warm up & Air Leak Test	Vacuum: 65mbar Test time: 15 min	270 °F	3 min	3 min	Empty chamber
Warm up	2 pulses	270°F	3 min	3 min	Empty chamber

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1. Only factory set sterilizing time should be utilized with medical devices intended for patient contact.
2. Factory set drying time. These are the minimum validated drying times, which may be extended depending on load conditions and wraps.
3. Recommended load: Refer to table 2 and 3. The load configurations listed in table 2 and 3 are those used during performance testing of the sterilizer models.
4. Fabric load should be preconditioned between 68°F and 75°F and at a relative humidity of at least 35% to 60% for at least 2 hours.
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The following tables show the recommended loads for the Belimed Steam Sterilizer MST-H:

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9-6-18 HS1	1 door	977	1080 x 660 x 2014	1970 x 1700 x 2330
9-6-18 HS2	2 doors	977	1080 x 660 x 2014	1970 x 1700 x 2330

Table 4: Models and dimensions

NONCLINICAL COMPARISON TO PREDICATE DEVICE:

The Belimed Steam Sterilizers MST-H, models 9-6-12, 9-6-15, and 9-6-18 are very similar to the predicate device.
A summary of the differences to the predicate device is included in Table 5 :

General Sterilizer Features	Belimed Steam Sterilizer TOP5000 Series 9-18 (K021223)	Belimed Steam Sterilizer MST-H	Substantially Equivalent or Different
Intended Use	Terminal Sterilization of non-porous and porous heat and moisture-stabile materials used in healthcare facilities	Terminal Sterilization of non-porous and porous heat and moisture-stabile materials used in healthcare facilities	Same
Operating Principle	The sterilizing agent of the Belimed Sterilizers MST-H is steam. Steam is made from demineralized water and is therefore non-toxic. Steam is the preferred method to sterilize porous an non-porous heat resistant materials and textiles in hospitals for more than 100 years. Preferred sterilization temperatures are 250 °F, 270 °F and 275 °F.	The sterilizing agent of the Belimed Sterilizers MST-H is steam. Steam is made from demineralized water and is therefore non-toxic. Steam is the preferred method to sterilize porous an non-porous heat resistant materials and textiles in hospitals for more than 100 years. Preferred sterilization temperatures are 250 °F, 270 °F and 275 °F.	Same
Product code C.F.R: code Class	FLE 880.6880 Steam Sterilizer II	FLE 880.6880 Steam Sterilizer II	
Built according to Standard	ANSI/AAMI ST8:1994 Hospital Steam Sterilizers	ANSI/AAMI ST8:2013 Hospital Steam Sterilizers	Substantially Equivalent, (ST8:2013 uses heavier instrument load and refers to new standard versions)
Electrical safety standard	UL 3101-1 IEC 61010-1 ed1, am1 IEC 61010-2-041 de1	UL IEC 61010-1: 2004, IEC 61010-2-040:2005	Substantially Equivalent
EMC conformity	IEC / EN 61326:2001 / 2002	IEC / EN 61326:2001 / 2002	Same
Electrical supply 9-6-9 &9-6-12 9-6-15 & 9-6-18	3 Phase 208V, 60Hz Max. current: 13A Max. current: 20A	3 Phase 208V, 60Hz Max. current: 13A Max. current: 20A	Same
Utility supply pressure requirement Steam Water Compressed air	 2.5 - 3 bar g 2 – 5 bar g 5 – 7- bar g	 2.5 – 3.5 bar g 2 – 5 bar g 5 – 7- bar	Substantially Equivalent

Steam capacity requirement: Model 9-6-9 Model 9-6-12 Model 9-6-15 Model 9-6-18	 120 kg/h 160 kg/h 200 kg/h 240 kg/h	 n/a 100 kg/h 120 kg/h 170 kg/h	Lower, Substantially Equivalent
Compressed air capacity requirement:	10 Nm^3/h	10 Nm^3/h	Same
Cooling water requirement: Model 9-6-9 Model 9-6-12 Model 9-6-15 Model 9-6-18	 2 m^3/h 2.5 m^3/h 3 m^3/h 3.5 m^3/h	 n/a 2.4 m^3/h 2.8 m^3/h 3.2 m^3/h	Lower, Substantially Equivalent
Control devices			
Vacuum device Model 9-6-9, 9-6-12 Model 9-6-15, 9-6-18	Water-ring vacuum pump 90 m^3/h 125 m^3/h	Water-ring vacuum pump 90 m^3/h 125 m^3/h	Same
Additional gas ejector / sterilizer runs with max. cooling water temperatures	No / 80 °F	Yes, if optional cooling water loop is not installed 90 °F	Substantially Equivalent
Steam condenser	Shell-and-tube heat exchanger, stainless steel	Shell-and-tube heat exchanger, stainless steel	Substantially Equivalent
Air Filtration	0,2um, efficiency >99.5% >99.97% for 0.3-micron particles	0,2um, efficiency >99.5% >99.97% for 0.3-micron particles	Same
Control valves for steam, vacuum and condensate	Stainless steel grade 316 L pneumatically driven piston-valves	Stainless steel grade 316 L pneumatically driven piston-valves	Substantially Equivalent
Control valves for cooling water	Brass Electric solenoid valves	Fiber-reinforced plastic material Electric solenoid valves	Substantially Equivalent
Piping material grade	AISI 316L	AISI 316L	Same
Pressure vessel			
Chamber and jacket material grade	AISI 316L	AISI 316L	Same
Chamber construction	Cubic welded structure with all-round heating ducts	Cubic welded structure with all-round heating ducts	Same
Chamber design pressure	39psi	40psi	Substantially Equivalent
Safety valves	Bronce, ASME approved	Bronce, ASME approved	Same
Chamber design standard	ASME Section VIII, Division 1, for unfired pressure vessels	ASME Section VIII, Division 1, for unfired pressure vessels	Same

Door material grade	AISI 321	AISI 321	Same
Door opening	Single or double door Horizontal door operation Motor driven	Single or double door Horizontal door operation Motor driven	Substantially Equivalent
Door safety: Door safety bar Additional door locking fixture Number of door limit switches	 Yes No Two 'door closed' switches per door	 Yes Yes one 'door closed' switch per door and one 'door closed & mechanically locked' switch per door	Substantially Equivalent
Door seal	Compressed air activated	Compressed air activated	Same
Chamber sizes Model: 9-6-9 9-6-12 9-6-15 9-6-18	 (H x W x D) in mm: 1080x660x1040 1080x660x1400 1080x660x1700 1080x660x2000	 (H x W x D) in mm: Not available 1080x660x1398 1080x660x1706 1080x660x2014	Substantially Equivalent
Control			
Control Technology	PLC	PLC	same
HMI Technology loading side	LCD color / 5,7"	TFT color 10"	Different, larger display
HMI Technology unloading side	BT2-2004 LCD display / h x w = 35mm x 68mm	LSC display / h x w=27mmx100mm	Substantially Equivalent
Printer Technology	Matrix Dot technology 42 char /line, paper width 57mm	Thermal technology 42 char /line, paper width 57mm	Substantially Equivalent (same Information on printout)
Process control	Automatic through all phases of a cycle	Automatic through all phases of a cycle	Same
Sterilization process control	Pressure controlled by an absolute pressure transmitter	Pressure controlled by an absolute pressure transmitter	Same
Sterilization process recording	Independent temperature and pressure sensors for recording	Independent temperature and pressure sensors for recording	Same
Sterilization process monitoring	Temperature sensor for exposure temperature monitoring	Temperature sensor for exposure temperature monitoring	Same
Process alarms	Detected errors cause an acoustic and visual alarm. Alarms are recorded on the printer. At cycle end the door on the unloading side (double door models) can't be opened. Alarms must be manually acknowledged on the load side operating panel.	Detected errors cause an acoustic and visual alarm. Alarms are recorded on the printer. At cycle end the door on the unloading side (double door models) can't be opened. Alarms must be manually acknowledged on the load side operating panel.	Same

Cycle phases	All cycle phases and sterilizer status are monitored on display. Display of: -Chamber temperature & pressure -Process status -Door status -Alarms, if pending	All cycle phases and sterilizer status are monitored on display. Display of: -Chamber temperature & pressure -Process status -Door status -Alarms, if pending Additional process status display for cycle state above the chamber (LED bar display)	Substantially Equivalent (Additional information)
Cycle end	Acoustic signal at cycle end Cycle end Indication on operating panel display.	Acoustic signal at cycle end Cycle end Indication on operating panel display.	Same
Performance:			
Performance: Biological performance (half cycle) Comply with	 SAL of 10^{-6} reduction Through achievement of no growth at half cycle with validation loads. AAMI ST8:1994	 SAL of 10^{-6} reduction Through achievement of no growth at half cycle with validation loads. AAMI ST8:2013	 Same
Moisture retention Comply with	Fabrics: <3% increase in pre-sterilization textiles test pack weight Instruments <20% increase in pre-sterilization towel weight of the test load AAMI ST8: 1994	Fabrics: <3% increase in pre-sterilization textiles test pack weight Instruments <20% increase in pre-sterilization towel weight of the test load AAMI ST8:2013	 Same
Factory predefined cycles			
Prevac 270°F Sterilize temperature Sterilize time Dry time No. of pre-vacuums Qualified according to Test Load Load capacity (trays) model 9-6-9 model 9-6-12 model 9-6-15 model 9-6-18	Yes 132°C / 270°F 4 minutes 20 minutes 4 AAMI ST8: 1994 Instrument load in double wrapped trays, full load 17lbs gross weight per tray 9 12 15 18	Yes 132°C / 270°F 4 minutes 30 minutes 5 (improved air removal) AAMI ST8:2013 Instrument load in double wrapped trays, full load 25 lbs gross weight per tray n/a 16 20 24	Substantially Equivalent

Prevac 270°F Sterilize temperature Sterilize time Dry time No. of pre-vacuums Qualified according to Test Load Load capacity (packs) model 9-6-9 model 9-6-12 model 9-6-15 model 9-6-18	Yes 132°C / 270°F 4 minutes 5 minutes 4 AAMI ST8: 1994 Single fabric pack 18 30 36 42	Yes 132°C / 270°F 4 minutes 5 minutes 5 (improved air removal) AAMI ST8:2013 Single fabric pack and full load n/a 32 40 48	Substantially Equivalent
Liquid 250°F Sterilize temperature Sterilize time Qualified according to Test Load Load capacity model 9-6-9 model 9-6-12 model 9-6-15 model 9-6-18	Yes 121°C / 250°F 45 minutes AAMI ST8:1994 Liquids in 1000ml in vented containers, 3 bottles Number of containers 126 168 210 252	Yes 121°C / 250°F 45 minutes AAMI ST8:2013 Liquids in 1000ml in vented containers, 3 bottles and full load Number of containers n/a 168 210 252	same
Prevac 275°F Sterilize temperature Sterilize time Dry time No. of pre-vacuums Qualified according to Test Load Load capacity model 9-6-12 model 9-6-15 model 9-6-18	n/a	Yes 135°C / 275°F 3 minutes 30 minutes 5 (improved air removal) AAMI ST8:2013 Instrument load in double wrapped, full load 25 lbs gross weight per tray 16 20 24	Different

Gravity 270°F Sterilize temperature Sterilize time Dry time Qualified according to Test Load Load capacity model 9-6-12 model 9-6-15 model 9-6-18	n/a	Yes 132°C / 270°F 15 minutes 30 minutes AAMI ST8:2013 Metal load in double wrapped trays, 25 lbs gross weight per tray 16 20 24	Different
BOWIE-DICK Test Sterilize temperature Sterilize time Dry time No. of pre-vacuums Qualified according to	Yes 134°C 3.5 minutes 3 minutes 4 AAMI ST8: 1994	Yes 134°C 3.5 minutes 3 minutes 5 AAMI ST8:2013	Substantially Equivalent
Air leak test Leak test Qualified according to	 Yes AAMI ST8: 1994	 Yes AAMI ST8:2013	Same
Warm-Up and leak test Qualified according to	Yes AAMI ST8: 1994 (air leak test)	Yes AAMI ST8:2013 (air leak test)	Same
Express 270°F Sterilize temperature Sterilize time Dry time Qualified according to Test Load	Yes, Prevac cycle 132°C / 270°F 4 minutes 3 minutes AAMI-ST8:1994 Single wrapped instrument tray with a single instrument	n/a	Different
Gravity 270°F Sterilize temperature Sterilize time Dry time Qualified according to Test Load	Yes Flash cycle 132°C / 270°F 3 minutes 1 minute AAMI-ST37:1996 Unwrapped instrument tray with a single instrument	n/a	Different

Gravity 270°F Sterilize temperature Sterilize time Dry time Qualified according to Test Load	Yes Flash cycle 132°C / 270°F 10 minutes 1 minute AAMI-ST37-1996 Unwrapped instrument tray with a non-porous multiple instruments, max. weight of 17lbs	n/a	Different

Table 5: Comparison to predicate device

CLINICAL DATA:

No clinical data is required for this device classification submission.

EFFECTIVENESS:

Efficacy of sterilizer function and exposure time recommendations are ultimately shown by complete kill of biological indicators and verifying an appropriate safety factor or sterility assurance level (SAL) of 10^{-6} reduction. Belimed Sauter AG validates its sterilization cycles by recommended practices, standards and guidelines developed by various independent organizations such as the Association for Advancement of Medical Instrumentation (AAMI). Prior to release, Belimed Steam Sterilizer MST-H, models 9-6-12, 9-6-15, and 9-6-18 were validated to meet the requirements of ANSI/AAMI ST8:2013.

The results of the Belimed Steam Sterilizer MST-H, models 9-6-12, 9-6-15, and 9-6-18 verification studies demonstrate that the sterilizers perform as intended and are summarized as follows:

- Empty chamber testing was performed as described in Section 5.4.2.5 of ANSI/AMMI ST8:2013, for the PreVac, Gravity and Liquid cycles. These cycles demonstrated the sterilizer's capability to provide steady state thermal conditions within the chamber that are corresponding with the predicted sterility assurance level (SAL) in the load. The sterilizer meets the temperature control requirements of Section 4.4.2.5 of ANSI/AAMI ST8.
- All PreVac 270 cycles were verified using a single fabric test pack for biological performance, as described in Section 5.5.2 ANSI/AAMI ST8:2013 were qualified according to section 5.5.2.5 of ANSI/AAMI ST8:2013. These cycles demonstrated a sterility assurance level (SAL) of 10^{-6} through achievement of no growth at half cycle with validation loads. Moisture retention of less than 3 % increase in pre-sterilization test pack weight was demonstrated with a single fabric pack and with full load fabrics, and no wet spots were examined, according to section 5.7.1.4 of ANSI/AAMI ST8:2013.
- All PreVac and Gravity instrument cycles were qualified according to section 5.5.4 of ANSI/AAMI ST8:2013. The tests were performed with full load instruments trays, 25lbs each. Instead of cotton wrappers, FDA cleared wrappers (double wrapped) were used. These cycles demonstrated a sterility assurance level of 10^{-6} through achievement of no growth at half cycle with validation loads, moisture retention of less than 20 % increase in pre-sterilization weight of the towel, and exhibited no wet spots on the outer wrapper according to section 5.7.2.4 of ANSI/AAMI ST8:2013.
- The Bowie Dick Test cycle was verified using the Bowie-Dick Test Pack was qualified according to section 5.6.1 of ANSI/AAMI ST8:2013 and demonstrated a uniform color change throughout the test sheet (FDA cleared test indicator) and the load temperature devices attained the exposure temperature within 10 seconds of progressing into the exposure phase.

- The liquid cycle was verified according to section 5.5.3 of ANSI/AAMI ST8:2013. This cycle demonstrated a sterility assurance level of 10^{-6} through achievement of no growth with validation loads and the temperature was above 121°C for at least 12 minutes. The loss of liquid did not exceed 70ml in a 1000ml bottle (unloading temperature 90°C). Additional tests with full load liquids showed the same results.
- The software validation for the cycle operation was performed according to FDA's moderate level of concern recommendations provided in the document *"Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices (May 2005)".*

Standards:

Belimed Sauter AG's sterilizers including the Belimed Steam Sterilizers MST-H, models 9-6-12, 9-6-15, and 9-6-18 have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The Belimed Steam Sterilizer MST-H complies with the following safety standards:

1. ANSI/AAMI ST8:2013
2. ANSI/AAMI ST79:2010 +A1:2010 +A2:2011 +A3:2012 +A4:2013
3. IEC EN 62304:2006
4. EN ISO 14971:2012
5. EN ISO 13485:2003+AC2009 Medical Devices – Quality management systems. Requirements for regulatory purposes
6. IEC EN 60601-1-2:2007
7. UL 61010-1:2004
8. IEC EN 61010-2-040:2005
9. American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels Ed. 2013

USER INFORMATION:

Belimed Sauter AG provides information to the user that is intended to insure safe and effective use of steam sterilization in its detailed Operating Instructions, Technical Manual and other labeling. Belimed Sauter AG also recommends the use and periodic review of the AAMI steam sterilization standards to ensure further assurance of the safe and effective use of steam sterilization equipment in health care facilities.

CONCLUSION:

The Belimed Steam Sterilizers MST-H, models 9-6-12, 9-6-15, and 9-6-18 are substantially equivalent devices to that of the predicate device. There have been no substantial changes in technology and intended use to the predicate device series 9-18 (K021223). This steam sterilizer MST-H, models 9-6-12, 9-6-15, and 9-6-18 meet the applicable requirements of the applicable standards.
Based on the provided information in this premarket notification, it can be concluded that the subject device is substantial equivalent to the predicate device.